

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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WILLIAM SMITH,

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Petitioner,

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No. 15-1194V

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Special Master Christian J. Moran

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v.

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Filed: February 28, 2019

SECRETARY OF HEALTH

*

AND HUMAN SERVICES,

*

Dismissal, insufficient proof.

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Respondent.

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Diana Lynn Stadelnikas, Maglio Christopher and Toale, PA, for petitioner
Claudia Gangi, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION¹

Mr. William Smith, represented by Ms. Diana Stadelnikas, filed a petition for compensation under the National Vaccine Injury Compensation Program on October 14, 2015. In his petition, Mr. Smith alleged that a flu vaccine administered on March 15, 2014, caused him to develop Guillain-Barre Syndrome (GBS). Petition at 1-2. Based upon an evaluation of the medical records, expert reports, and statements from treating physicians, the undersigned recently ruled that preponderant evidence supported the conclusion that Mr. Smith did not suffer from GBS following his vaccination. Ruling, issued Oct. 31, 2018. Mr. Smith now moves for the dismissal of his petition. For the following reasons, Mr.

¹ Because this ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the ruling.

Smith's motion is GRANTED and his petition is DISMISSED for insufficient proof pursuant to Vaccine Rule 8(d).

Factual Summary

The facts of this case were reviewed, in detail, in the October 31, 2018 ruling regarding Mr. Smith's diagnosis and are restated here.

Prior the vaccination in question, Mr. Smith had a complex medical history that included type 2 diabetes. Mr. Smith was not compliant with the treatments prescribed for his diabetes and his disease was considered "uncontrolled." Exhibit 4 at 12. He suffered from various symptoms that were secondary to his diabetes, including ulcers and osteomyelitis in his toe, diabetic neuropathy, and diabetic retinopathy. Exhibit 1 at 4, 6; exhibit 2 at 4; exhibit 3 at 3.

Two days before the vaccination in question, on March 12, 2014, Mr. Smith experienced shortness of breath, signs of heart failure, swollen ankles, anemia, hypokalemia, and acute renal failure. Exhibit 4 at 29-30. He was admitted to the hospital for these issues on March 13, 2014. *Id.* at 31. On March 14, 2014, he was administered the flu vaccine into his right arm during the course of his hospitalization. Exhibit 7 at 209.

On March 25, 2014, after being discharged from the previous hospitalization, Mr. Smith was admitted to the Medina Hospital for sudden weakness in his legs that began that morning. Exhibit 5 at 175-76. On admission, although it was noted that the etiology of the leg weakness was uncertain, the physician remarked that Mr. Smith had recently been administered the flu vaccine, which is "[one] of the risk factors for something such as GBS." *Id.* at 176. During the course of Mr. Smith's admission to the Medina Hospital, his treating neurologist, Dr. Eric Baron, noted that the possibility of GBS was part of Mr. Smith's differential diagnosis and several tests were run at Medina Hospital to try to determine whether GBS was the cause of Mr. Smith's symptoms. *See* exhibit 5 at 178. Based on the results from these tests, notably a test on Mr. Smith's cerebrospinal fluid (CSF), as well as Mr. Smith's "mixed clinical picture," Dr. Baron decided to not move forward with treatment for GBS due to his "lower suspicion for GBS" following examination and testing. *Id.* at 201.

On March 27, 2014, Mr. Smith was transferred from Medina Hospital to the main campus of the Cleveland Clinic Hospital System because Medina did not have the necessary diagnostic tools or care for Mr. Smith. Id. At the main campus, he was seen by Dr. Tina Waters, Dr. Donika Patel, and Dr. Jessica Rundo, among others. On his initial evaluation by Dr. Waters, she noted that the tests had been inconclusive in determining if Mr. Smith's pathology was central or peripheral in nature. Exhibit 9 at 19-20. She recommended additional testing, including nerve conduction studies. Id.

On March 30, 2014, while still admitted to the hospital, Mr. Smith woke up with worsened weakness in his right leg and new weakness in his right arm. Exhibit 9 at 52. An MRI revealed that Mr. Smith had suffered a stroke, which caused the additional weakness. Id. However, the cause of Mr. Smith's initial symptoms remained unidentified. Id. at 58.

Additional medical testing was performed during the course of Mr. Smith's stay at the Cleveland Clinic main campus. These tests appeared to rule out GBS as the cause of Mr. Smith's symptoms. For instance, during a neuromuscular consultation with Dr. Patel on April 2, 2014, Dr. Patel noted that there was not strong evidence of an acute peripheral nerve injury causing his symptoms. Exhibit 9 at 35. Instead, Dr. Patel concluded that Mr. Smith had "severe generalized polyneuropathy" that she associated with Mr. Smith's diabetes. Id. She concluded that GBS was a "less likely" diagnosis. Id.

Dr. Rundo also concluded, based on a second examination of Mr. Smith's CSF as well as the nerve conduction studies and a physical exam, that Mr. Smith was not suffering from an acute peripheral nerve disease. Id. at 72.

Mr. Smith was discharged from the hospital on April 4, 2014, with a diagnosis of lower extremity weakness and acute stroke. Exhibit 9 at 7. The discharge papers state that the treating physicians did not have a definitive conclusion about the etiology of Mr. Smith's condition, but the record does state that "neuromuscular specialists were consulted, and they attribute the symptoms to possibly diabetic neuropathy." Id. at 9. Following his discharge, Mr. Smith was transferred to an inpatient rehabilitation facility at Lodi Community Hospital (LCH).

On intake at LCH, the records show that Mr. Smith's chief complaint was that he had suffered from GBS and a stroke. Exhibit 8 at 32. The records even state that Mr. Smith was "diagnosed with Guillain-Barre syndrome" and should no longer be administered the flu vaccine. *Id.* at 32, 44. However, the source of this information and other references to GBS from the LCH records is not obvious. It is also notable that subsequent medical records from Dr. Cullen, Mr. Smith's primary care physician, incorporated GBS into Mr. Smith's past medical history. See, e.g., exhibit 11 at 6, 7.

Procedural History

Mr. Smith filed his petition for compensation on October 14, 2015. Based on the claims in Mr. Smith's petition, his case was initially assigned to the Special Processing Unit (SPU) under supervision of the Chief Special Master.

Mr. Smith filed a statement confirming that the documentary evidence was sufficient for the respondent's review on April 11, 2016. Respondent filed his Rule 4(c) report stating his position in the case on June 27, 2016. In his report, respondent argued, *inter alia*, that Mr. Smith was not entitled to compensation under the Act because he was "neither diagnosed with nor treated for GBS." Resp't's Rep., filed June 27, 2016, at 8.

Based on the dispute regarding Mr. Smith's diagnosis, petitioner was ordered to file an expert report if he intended to proceed with his petition. Order, issued June 30, 2016. Multiple enlargements of time were requested and granted for the report. Petitioner ultimately filed a report from a neurologist, Dr. Thomas Morgan, on January 3, 2017. See exhibit 16. Respondent then requested the opportunity to file a rebuttal report and, after receiving an enlargement of time to do so, filed a report from his expert neurologist, Dr. Daniel Feinberg, on May 10, 2017. See exhibit A. After respondent's report was filed, Mr. Smith's case was transferred out of SPU and randomly assigned to the undersigned special master. Order, issued May 10, 2017.

Upon reassignment, the undersigned held a status conference on June 14, 2017, to discuss the parties' expert reports. The undersigned communicated that both reports did a poor job of explicating on the underlying diagnostic criteria for the petitioner's claimed injury and that the parties should file supplemental reports from each of their experts addressing this deficit. Order, issued June 15, 2017.

Respondent filed his supplemental report on August 15, 2017 (exhibit C), and petitioner filed his supplemental report on October 16, 2017 (exhibit 23).

During a status conference on October 26, 2017, the parties agreed that they should proceed to brief the outstanding question of Mr. Smith's diagnosis so that a finding of fact as to that issue could be made. Order, issued Nov. 22, 2017. The undersigned issued a scheduling order for the parties' briefs. Id. The parties complied with the deadlines in the scheduling order.

An evaluation of the parties' briefs and the expert reports submitted in Mr. Smith's case emphasized the fact that the parties held different interpretations of how Mr. Smith's treating physicians characterized his disease. Compare Pet'r's Mot., filed Jan. 26, 2018, at 4 (noting that Dr. Morgan's opinion that Mr. Smith suffered from AMSAN / GBS was consistent with the opinion of Mr. Smith's treating neurologists) with Resp't's Resp., filed March 16, 2018, at 4-6 (noting that Mr. Smith's treating physicians *did not* diagnose Mr. Smith with GBS). Because of the importance of the opinion of treating physicians, especially as it pertains to questions of diagnosis, the undersigned ordered the parties to jointly draft letters to Mr. Smith's treating physicians, seeking information that may prove helpful for the question at bar. See order, issued Apr. 27, 2018 (citing 42 U.S.C. § 300aa-12(d)(3)(B) (authorizing special masters to seek information)).

Of four doctors that the parties sent letters to, only two responded: Dr. Eric Baron and Dr. Jessica Rundo. Both physicians provided opinions that were inconsistent with petitioner's argument that he suffered from, and was diagnosed with, GBS following the vaccination. See exhibits 25-26. In a status conference held following the filing of the letters from Dr. Rundo and Dr. Baron, petitioner stated a desire to file a rebuttal from Dr. Morgan, his expert. See order, issued Sep. 5, 2018. The undersigned granted the petitioner 30 days to do so. Id. Mr. Smith filed a supplemental report from Dr. Morgan on October 4, 2018. In his report, Dr. Morgan attempted to discredit the value of the treating physicians' opinions. See exhibit 27.

Based on the totality of the record, the undersigned ruled that "Mr. Smith did not suffer the injury he alleged, but instead manifested a disease course that was consistent with his pre-existing chronic conditions as well as with the stroke he experienced during the course of his hospitalization." Ruling, issued October 31, 2018. Mr. Smith was provided 30 days to file a status report on his next steps. Id.

On November 30, 2018, petitioner moved for a stay of proceedings to allow him time to find new counsel. Petitioner's motion was granted. Order, issued December 6, 2018. On January 4, 2019, Ms. Stadelnikas moved to withdraw as Mr. Smith's attorney, citing "irreconcilable differences" between her and the petitioner. On that same date, petitioner moved for an award of interim fees and costs and on February 25, 2019, the Secretary responded to the fees motion.²

On February 27, 2019, Ms. Stadelnikas moved to strike her motion to withdraw as Mr. Smith's attorney. Ms. Stadelnikas's motion stated that Mr. Smith had authorized the filing of additional pleadings related to his petition. Concurrently, Mr. Smith moved to strike his motion for interim fees and costs. The undersigned granted both motions. Order, issued Feb. 27, 2019.

Also on February 27, 2019, Mr. Smith moved to dismiss his petition. In his motion, petitioner stated that "an investigation of the facts and science supporting his case" demonstrated that he would not be able to prove his entitlement to compensation. Pet'r's Mot., filed Feb 27, 2019, at 1. This motion is now ripe for adjudication.

Analysis and Conclusion

As noted in the October 31, 2018 ruling, Mr. Smith has an affirmative burden to show that he has the injury he is seeking compensation for. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011); see also Hibbard v. Sec'y of Health and Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) ("[i]f a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by 'reputable medical or scientific explanation,' by which a vaccine can cause the kind of injury that the petitioner claims to have suffered"). Because Mr. Smith

² The deadline for the Secretary's response was extended due to the government shutdown. See General Order, issued Jan. 29, 2019.

seeks compensation for GBS and / or a GBS variant, it was his affirmative duty to establish by preponderant evidence that he suffered from that condition.

For the reasons stated in the October 31, 2018 ruling, Mr. Smith has not met this burden. The record, instead, reflects that Mr. Smith's condition following the vaccination had no relation to GBS or a GBS variant, but was instead completely explained as a manifestation of his pre-existing disease in conjunction with a small stroke experienced during his hospitalization. Because Mr. Smith cannot establish by preponderant evidence that he suffered from the injury he seeks compensation for, he is not entitled to compensation under the Act. See Hibbard, 698 F.3d at 1365. Accordingly, Mr. Smith's petition is DISMISSED pursuant to Vaccine Rule 8(d).

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master